availability of a guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' This guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' This guidance provides information on (1) Qualifying impurities found in a drug substance used in an ANDA by a comparison with impurities found in the related *U.S. Pharmacopeia* (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in a drug substance used for an ANDA than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying impurities in a drug substance used for an ANDA that are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels below which qualification is *not* needed.

In the **Federal Register** of July 24, 1998 (63 FR 39880), FDA announced the availability of a draft version of this guidance. The July 1998 document gave interested persons an opportunity to submit comments through September 22, 1998. On October 19, 1998 (63 FR 55876), in response to requests from the public, the agency reopened the comment period until November 23, 1998. All comments received during the comment period have been carefully reviewed and the guidance was revised, where appropriate.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0038]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A; *Form No.:* HCFA-R–38;

Use: This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation.

Frequency: Other (Initial application for Medicare);

Affected Public: Individuals or households; business or other for profit; not for profit institutions; farms; Federal Government; and State, Local or Tribal Government;

Number of Respondents: 3,538;

Total Annual Hours: 9,456.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 22, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–31325 Filed 12–2–99; 8:45 am]

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